



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,342	03/01/2004	Lon S. Weiner	M913.12-7	9417
40306	7590	12/28/2007		
SHEWCHUK IP SERVICES 3356 SHERMAN CT. STE. 102 EAGAN, MN 55121			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,342

Applicant(s)

WEINER ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 14, 16, 35 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-13, 15, 17-34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-13, 15, 17, 18, 21, 28-32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichty (US Pat. 4,456,005).

Lichty discloses a method of repairing a fractured bone, comprising: advancing a device through a bone fragment (Fig. 2), the device having an elongated shaft extending longitudinally about a shaft axis (Fig., 2), the device comprising: a bone exterior section (Fig. 2, near ref. 10) extending longitudinally about the shaft axis and making up at least one third of a total length of the device (Fig. 2); and a bone penetration section (Fig. 2, near ref. 16) extending distally from the bone exterior section, the bone penetration section comprising: a non-engaging fragment section extending longitudinally about the shaft axis (Fig. 2, proximal portion of ref. 16); and a bone anchor section (Fig. 2, distal portion of ref. 16) extending longitudinally about the shaft axis and located distally to the non-engaging fragment section (Fig. 2), the bone anchor section having threads for engagement with the anchor bone (Fig. 2, near ref. 16), with a major diameter of the threads being greater than a shaft diameter of the non-engaging fragment section (Fig. 2); and a compression engagement (Fig. 2, ref. 14) on a distal end of the bone exterior section (Fig. 2), the compression engagement providing

a shoulder (Fig. 2, bottom and side surfaces of ref. 14) extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment (Fig. 2); and screwing the device such that the bone anchor section advances into an anchor bone (Fig. 2) with the fragment section in the bone fragment and with the bone exterior section extending outside the bone (Fig. 2), thereby connecting the bone fragment to an anchor bone for a healing duration and extending out of the bone during the healing duration (column 3, lines 37-45). The bone exterior section is longer than the bone anchor section (Fig. 2). The bone exterior section is more than 45% of a total length of the device (Fig. 2). The bone exterior section has threads of a shallower pitch than the threads of the bone anchor section (Fig. 2), and wherein the compression engagement is provided by a nut rotatably supported on the threads of the bone exterior section (Fig. 2). The bone exterior section has external threads which mate with internal threads on the compression engagement (Fig. 2), and wherein the inside diameter of the internal threads on the compression engagement is smaller than the non-engaging fragment section such that the internal threads on the compression engagement cannot advance onto the non-engaging fragment section (Fig. 2). The bone exterior section has threads of a different thread profile than the threads of the bone anchor section (Fig. 2), and wherein the compression engagement is provided by a nut rotatably supported on the threads of the bone exterior section (Fig. 2). The shaft of the non-engaging fragment section is substantially smooth and cylindrical (Fig. 2). The threads on the bone anchor section are self-tapping distally for insertion (Fig. 2). The threads on the bone anchor section are self-tapping proximally for removal (Fig. 2). The shaft of the non-engaging

fragment section is substantially smooth and cylindrical (Fig. 2). The threads on the bone anchor section are self-tapping distally for insertion and self-tapping proximally for removal (Fig. 2). The bone anchor section ends in a distal drill tip (Fig. 2) adapted for insertion in bone without pre-drilling, and wherein the advancing and screwing acts are performed without pre-drilling (column 3, lines 56-60).

Lichty discloses a method of repairing a fractured bone comprising: advancing a device through a bone fragment (Fig. 2), the device having an elongated shaft (Fig. 2) extending longitudinally about a shaft axis, the device comprising: a bone exterior section (Fig. 2, near ref. 10); and a bone penetration section (Fig. 2, near ref. 16) extending distally from the bone exterior section, the bone penetration section comprising: a non-engaging fragment section (Fig. 2, proximal portion of ref. 16); and a bone anchor section (Fig. 2, distal portion of ref. 16) located distally to the non-engaging fragment section (Fig. 2), the bone anchor section having threads for engagement with the anchor bone (Fig. 2), with a major diameter of the threads being greater than a shaft diameter of the non-engaging fragment section (Fig. 2); and a compression engagement on the bone exterior section (Fig. 2, ref. 14), the compression engagement providing a shoulder (Fig. 2, bottom and side surfaces of ref. 14) extending at a substantial angle to the shaft axis for substantial contact with an exterior surface of the bone fragment, the compression engagement being axially movable on the bone exterior section (Fig. 2); and screwing the device such that the bone anchor section advances into an anchor bone (Fig. 2) with the fragment section in the bone fragment and with the bone exterior section extending outside the bone (Fig. 2), thereby

connecting the bone fragment to an anchor bone (Fig. 2) for a healing duration and extending out of the bone with the compression engagement in contact with the exterior surface of the bone fragment during the healing duration (Fig. 2).

Lichty discloses a method of repairing a fractured bone, comprising: advancing a threaded compression device through a bone fragment (Fig. 2), the threaded compression device comprising: a shaft running longitudinally from a proximal end to a distal end about a shaft axis (Fig. 2), the shaft comprising: an anchor section (Fig. 2, distal portion of ref. 16) extending longitudinally about the shaft axis on the distal end of the shaft (Fig. 2) the anchor section having threads with a major diameter and a minor diameter (Fig. 2, proximal threads with larger diameter and distal threads with smaller diameter); a non-engaging fragment section (Fig. 2, proximal portion of ref. 16) extending longitudinally about the shaft axis proximal to the anchor section (Fig. 2), the non-engaging fragment section having a diameter which is no greater than the minor diameter of the anchor section such that the non-engaging fragment section can fit within a profile drilled by the anchor section (Fig. 2); and an exterior section (Fig. 2, near ref. 10) extending longitudinally about the shaft axis proximal to the non-engaging fragment section, the exterior section having a length which makes up at least one third of the length of the shaft (Fig. 2); and a compression shoulder (Fig. 2, ref. 14) adapted for mounting on a distal end of the exterior section of the shaft at a longitudinally adjustable position (Fig. 2), the compression shoulder providing a contact surface (Fig. 2, bottom and side surfaces of ref. 14) which extends at an angle to the shaft axis for making contact with an exterior surface of the fragment ; and screwing the threaded

compression device such that the bone anchor section advances into an anchor bone (Fig. 2) with the fragment section in the bone fragment and with the exterior section extending outside the bone (Fig. 2), thereby connecting the bone fragment to an anchor bone for a healing duration (Figs. 2-4) and extending out of the bone with the compression engagement in contact with the exterior surface of the bone fragment during the healing duration (column 3, lines 37-45).

Lichty discloses a method of assisting in bone healing and growth, comprising: advancing a device through a bone fragment (Fig. 2), the device running from a proximal end to a distal end about a longitudinal axis (Fig. 2), the device comprising: an anchor section on the distal end (Fig. 2, distal portion of ref. 16), the anchor section having threads with a major diameter and a minor diameter (Fig. 2, proximal threads with larger diameter and distal threads with smaller diameter); a non-engaging fragment section (Fig. 2, distal portion of ref. 16) proximal to the anchor section (Fig. 2), the non-engaging fragment section having a smooth outer profile (Fig. 2) with a diameter which is no greater than the minor diameter of the threads of the anchor section (Fig. 2); a compression engagement proximal to the non-engaging fragment section (Fig. 2, ref. 14), the compression engagement having a shoulder (Fig. 2, bottom and side surfaces of ref. 14) which extends at an angle relative to the longitudinal axis (Fig. 2). The device further comprises a pointed proximal tip, and further comprising using the pointed proximal tip for drilling through bone in a reverse direction.

Lichty discloses a method of repairing a fractured bone, comprising: advancing a threaded compression device through a bone fragment (Fig. 2), the threaded

compression device comprising: a shaft running from a proximal end to a distal end about a shaft axis (Fig. 2), the shaft comprising: a distal drill tip for forward insertion (Fig. 2, distal-most portion); an anchor section on the distal end of the shaft next to the distal drill tip (Fig. 2, distal portion near ref. 16), the anchor section having threads with an anchor thread pitch (Fig. 2); a proximal threaded shaft section (Fig. 2, portion near ref. 10) proximal to the anchor section, the proximal threaded shaft section having threads with a compression thread pitch (Fig. 2), the compression thread pitch being different than the anchor thread pitch (Fig. 2); and a proximal drill tip for reverse insertion (Fig. 2, near ref. 22); and a compression shoulder (Fig. 2, ref. 14) adapted for mounting on the proximal threaded shaft section at an axially adjustable position (Fig. 2), the compression shoulder providing a contact surface (Fig. 2, bottom and side surfaces of ref. 14) which extends at an angle to the shaft axis for making contact with an exterior surface of the fragment; and screwing the threaded compression device such that the anchor section advances into an anchor bone (Fig. 2) with the fragment section in the bone fragment (Fig. 2) and with the compression shoulder contacting an exterior surface of the bone (fig. 2), thereby connecting the bone fragment to the anchor bone with the compression engagement in contact with the exterior surface of the bone for a healing duration (Figs. 2-4).

Lichty discloses a method of repairing a fractured bone comprising: advancing a reverse-taper threaded compression device through a bone fragment (Fig. 2), the compression device comprising: an elongated shaft running from a proximal end to a distal end about a shaft axis (Fig. 2), the shaft comprising: an anchor section on the

distal end of the shaft (Fig. 2, distal portion of ref. 16), the anchor section having external threads for engagement with the anchor substrate (Fig. 2) with an anchor major diameter (Fig. 2, proximal threads with larger diameter) and an anchor minor diameter (Fig. 2, minor diameter of the shaft); and a fragment exterior section proximal to the anchor section (Fig. 2, proximal portion of ref. 16), the fragment exterior section having external threads (Fig. 2) with a fragment exterior major diameter (Fig. 2) and a fragment exterior minor diameter (Fig. 2); and a compression engagement (Fig. 2, ref. 14) adapted for mounting on the fragment exterior section, the compression engagement providing a contact surface (Fig. 2, bottom and side surfaces of ref. 14) which extends at an angle to the shaft axis for making contact with an exterior surface of the fragment (Fig. 2), the compression engagement having internal threads for mating with the external threads of the fragment exterior section enabling the compression engagement to be axially movable on the fragment exterior section (Fig. 2); and screwing the threaded compression device such that the anchor section advances into an anchor bone with the fragment section in the bone fragment and locating the compression shoulder in contact with an exterior surface of the bone (Figs. 2-4)e, thereby placing a compression force on the bone fragment against the anchor bone (Figs. 2-4). The threads on the anchor section are self-tapping distally for insertion (Fig. 2). The threads on the anchor section are self-tapping proximally for removal (Fig. 2).

Lichty discloses a method of repairing a fractured bone, comprising: screwing a device through a bone fragment (Fig. 2), the device comprising: an elongated shaft (Fig. 2) having a bone penetration section (Fig. 2, near ref. 16) extending distally from a bone

exterior section (Fig. 2, near ref. 10) about a shaft axis (Fig. 2), the bone penetration section being shorter than the bone exterior section (Fig. 2), the bone penetration section including a fragment section (Fig. 2, proximal portion of ref. 16) and a bone anchor section (Fig. 2, distal portion of ref. 16) located distally to the fragment section (Fig. 2), the bone anchor section having threads with a major diameter being greater than a diameter of the fragment section (Fig. 2); and a compression engagement (Fig. 2, ref. 14) on a distal end of the bone exterior section, the compression engagement providing a shoulder (Fig. 2, bottom and side surfaces of ref. 14) extending at a substantial angle to the shaft axis (Fig. 2); and further screwing the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment and with the bone exterior section extending outside the bone with a length extending outside the bone longer than the bone penetration section, since, depending on the angle of insertion of the device, the bone exterior section would extend out of the bone further than the length of the bone penetration section. The method further comprises, with the bone anchor section advanced into the bone fragment, but prior to the act of further screwing the device into the anchor bone, manipulating the bone exterior section to reposition or bias the bone fragment relative to the anchor bone, since this necessarily must be done as the surgeon reduces the fracture in order to properly align the bones. The method further comprises after the manipulating act, holding the bone exterior section in a desired alignment during the further screwing act (Figs. 2-4). After the further screwing act: the fragment section extends through the bone fragment without threaded engagement with the bone

fragment; and the threads of the bone anchor section are in engagement with the anchor bone; and the compression engagement is in substantial contact with an exterior surface of the bone fragment to bias the bone fragment toward the anchor bone (Fig. 2). The method further comprises moving the compression engagement axially on the elongated shaft to position the compression engagement in an axial position to make substantial contact with an exterior surface of the bone fragment when the bone anchor section advanced to a final position (Fig. 2). The method further comprises monitoring torque applied during the further screwing act (Fig. 2), since device into the bone.

Lichty discloses a method of using a reverse-taper threaded compression device for placing a compression force on a fragment against an anchor substrate (Fig. 2), the method comprising: advancing an anchor section (Fig. 2, distal portion of ref. 16) disposed on a distal end of a shaft of the compression device into the anchor substrate (Fig. 2), such that external threads on the anchor section engage the anchor substrate (Fig. 2); advancing a compression engagement (Fig. 2, ref. 14) disposed on a fragment exterior section (Fig. 2, near ref. 10) proximal to the anchor section relative to the shaft, such that the compression engagement makes contact with an exterior surface of the fragment (Fig. 2) to bias the fragment toward the anchor substrate (Figs. 2-4). The method further comprises removing the compression device from the anchor substrate by placing a reverse torque on the compression engagement (column 3, lines 37-45).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lichty (US Pat. 4,456,005).

Lichty discloses the claimed invention except for the screwing act and the further screwing act occur in a reverse direction such that the device is inserted into the anchor bone prior to engaging the bone fragment, while the moving the compression engagement axially on the elongated shaft occurs in a forward direction, opposite to the direction the device was introduced to the bone. It would have been obvious to a person having ordinary skill in the art to have reversed the steps of Lichty, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lichty (US Pat. 4,456,005) in view of Kambin (US Pat. 5,242,443).

Lichty discloses the claimed invention except for the device is provided in a kit of a plurality of such devices each having a different length of non-engaging fragment section.

Kambin discloses a kit of threaded bone devices (abstract) that comprise differing lengths (column 3, lines 59-62). This allows the surgeon to choose from a variety of lengths to accommodate varying anatomies.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Lichty within a kit that contained devices of varying lengths, in order to provide the surgeon with various devices to choose from in order to accommodate different anatomies.

Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichty (US Pat. 4,456,005) in view of Pierce (US Pat. 2,760,488).

Lichty discloses the claimed invention except for removing a portion of the bone exterior section so the bone exterior section does not extend as far outside the patient's tissue.

Pierce discloses removing a portion of a bone exterior section of the device (column 2, lines 54-60) so that the device is contained entirely under the skin of the patient (column 2, lines 54-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Lichty with the step of removing a portion of a bone exterior section of the device as taught by Pierce so that the device is contained entirely under the skin of the patient (column 2, lines 54-60).

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichty (US Pat. 4,456,005) in view of Pennig (US Pat. 5,709,687).

Lichty discloses the claimed invention except for a rotation section proximal to the compression engagement for rotating the anchor section, the rotation section having a smooth outer diameter; and using the smooth outer diameter of the rotation section to screw the device such that the bone anchor section advances into an anchor bone with the fragment section in the bone fragment and with the shoulder of the compression engagement abutting an exterior bone surface. Lichty does disclose using a wrench with the device in order to screw the device into a bone (column 2, line 68 and column 3, lines 1-4).

Pennig discloses a bone device (Fig. 1)(abstract) which comprises a smooth proximal section (Fig. 1, ref. 1).that is used with a rotary power tool with a chuck (column 8, lines 35-42), the smooth proximal section and the rotary power tool being used to screw the device into a bone (column 8, lines 35-52).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the wrench mechanism of Lichty with the smooth-walled proximal section of Pennig, in order to achieve the predictable result of screwing the device into a bone (column 8, lines 35-52).

Lichty in view of Pennig discloses the claimed invention except for the shoulder being at a diameter greater than the major diameter of the threads of the anchor section. It would have been an obvious matter of design choice to have constructed the shoulders as having a larger diameter than the threads of the anchor section, since

such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichty (US Pat. 4,456,005) in view of Huebner (US Pat. 6,030,162).

Lichty discloses the claimed invention except for the fragment exterior minor diameter is less than the anchor minor diameter. The fragment exterior major diameter is no greater than a mean of the anchor major diameter and the anchor minor diameter. The fragment exterior major diameter is no greater than the anchor minor diameter.

Huebner discloses a compression devices that has a varying diameter and varying thread diameters (Fig. 22), which aids in generating axial compression (column 4, lines 35-44).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the sections of Lichty with varying diameters and thread diameters as taught by Heubner, in order to aid in generating axial compression (column 4, lines 35-44).

Response to Arguments

Applicant's arguments, see remarks (pages 13-15), filed 10/02/2007 and interview summary (10/05/2007) are persuasive. Therefore, the rejection has been

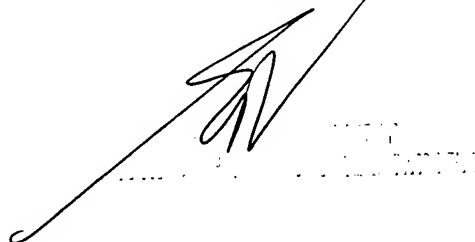
withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lichty (US Pat. 4,456,005).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EDUARDO ROBERT
Supervisor